

16024224

Summary of Safety and Effectiveness
Liquichek™ Anti-Smooth Muscle Control, Positive

1.0 **Submitter**

JAN 15 2003

Bio-Rad Laboratories
9500 Jeronimo Road,
Irvine, California 92618-2017
Telephone: (949) 598-1200
Fax: (949) 598-1555

Contact Person

Yvette Lloyd
Senior Regulatory Affairs Specialist
Telephone: (949) 598-1465

Date of Summary Preparation

December 20, 2002

2.0 **Device Identification**

Product Trade Name: Liquichek™ ANA Control Speckled Pattern, Positive
Common Name: Antinuclear Antibody, Indirect Immunofluorescent,
Antigen, Control
Classifications: Class II
Product Code: 82DBE
Regulation Number: 21 CFR 866.5100

3.0 **Device to Which Substantial Equivalence is Claimed**

Kallestad™ Autoantibody Positive Control
Bio-Rad Laboratories

510 (k) Number: K792610

4.0 **Description of Device**

This product is prepared from human serum with added preservatives. The control is provided in liquid form for convenience.

5.0 **Statement of Intended Use**

The new Liquichek™ Anti-Smooth Muscle Control, Positive, is intended for use as an unassayed quality control to monitor indirect immunofluorescent testing for the detection of smooth muscle autoantibodies.

6.0 **Comparison of the new device with the Predicate Device**

This control is substantially equivalent to the following quality control material for autoimmune analysis that is currently in the market:

Kallestad™ Autoantibody Positive Control
Bio-Rad Laboratories

510 (k) Number: K792610

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Liquichek™ Anti-Smooth Muscle Control, Positive (New Device)	Kallestad™ Autoantibody Positive Control (Predicate Device)
Similarities		
Intended Use	The Liquichek™ Anti-Smooth Muscle Control, Positive, is intended for use as an unassayed quality control to monitor indirect immunofluorescent testing for the detection of smooth muscle autoantibodies.	The Autoantibody Positive Control is a replacement reagent in the Kallestad Fluorescent Autoantibody test with mouse kidney, mouse stomach/kidney, Hep-2 cell line, or Crithidia lucilliae substrates.
Matrix	Human Serum	Human Serum
Storage (Unopened)	2°C to 8°C until expiration date	2°C to 8°C until expiration date
Form	Liquid	Liquid



DEPARTMENT OF HEALTH & HUMAN SERVICES

JAN 15 2003

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Yvette Lloyd
Senior Regulatory Affairs Specialist
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, California 92618-2017

Re: k024224
Trade/Device Name: Liquichek™ Anti-Smooth Muscle Control, Positive
Regulation Number: 21 CFR § 866.5120
Regulation Name: Anti-Smooth Muscle Antibody, Indirect Immunofluorescent, Antigen, Control
Regulatory Class: II
Product Code: DBE
Dated: December 20, 2002
Received: December 23, 2002

Dear Ms. Lloyd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

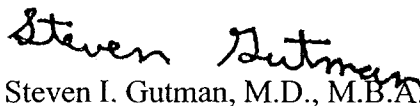
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,


Steven I. Gutman, M.D., M.B.A.

Director

Office of In Vitro Diagnostic Device
Evaluation and Safety

Center for Devices and Radiological Health

Enclosure

510 (k) Number (if known): K024224

Device Name: **Liquichek™ Anti-Smooth Muscle Control, Positive**

Indications for Use:

The new Liquichek™ Anti-Smooth Muscle Control, Positive, is intended for use as an unassayed quality control to monitor indirect immunofluorescent testing for the detection of smooth muscle autoantibodies.

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ☒ or Over-the Counter use ☐

J. P. Rivera for J. B. Antista
(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K024224